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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,729	01/16/2004	Randall B. Lauffer	13498-019003	6363

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,729

Applicant(s)

LAUFFER ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 18 and 22-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-17 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

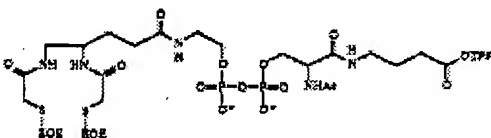
- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/16/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Election

The election without traverse of the species of prodrug compound 2 on page 37 is acknowledged. Applicant states that claims 1-4, 8-17 and 19-21 read on the elected species.

NOTE: after no prior art was found to reject the species elected by the applicant, the examiner in accordance with Markush practice elected another species within the scope of the claims. This species is the contrast agent as follows:



(e.g., which is within the scope of claim 2, wherein the IEM is the N2S2 chelate, the PBM is the polypeptide, TFP and the MS is P-O).

NOTE: The claims have only been searched to the extent that they are drawn to applicant's elected species and the species above, which is relied upon in the art rejection below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8-17 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the claims cannot be determined because the contrast agent is defined by function only in claim 1 and there are no components or means present in the claim to provide for such function. Also the claims are incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are the relationship of the IEM, the PBM and the MS, as it is not clear how they are connected or even if they are connected or what additional chemical

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moieties may be used for connection of these groups. It is unclear what components are required in the claims or what contrast agents (e.g., compounds, liquids, etc. can be used thereas) would be included or excluded by this recitation of functionality which is present only after administration to the body or how or when such "bioactivation" occurs. It is not possible to determine from claim 1 what contrast agents are encompassed by this vague functional recitation.

The dependent claims fall therewith as being dependent on rejected claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brixner (US 5,094,848).

Brixner discloses contrast agents of the formula A-bridging moiety-targeting moiety in column 2. Brixner discloses the contrast agent as shown in example 1, which is directly within the scope of the claimed contrast agents. For example, in the compound of example 1, the chelate moiety corresponds to an image-enhancing moiety (as defined thereby by the specification), the peptide (TFP) corresponds to the PBM (which is defined in the specification on page 20 as being a peptide) and the phosphate containing moiety corresponds to the modification site (MS) as it has a phosphorus-oxygen bond which the defined as the MS on page 31 of the specification. Brixner discloses that the chelates may contain paramagnetic metals for methods of MRI, (and cites US 4,647,447, which includes DPTA and Gd), see column 18, lines 31 and column 15, lines 46+. The phosphate bond of the contrast agents is cleaved in vivo, thereby separation the targeting moiety and IEM, which would clearly be within the scope of a prodrug having a lower affinity for tissue protein than the bioactivated form, since the polypeptide is

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cleaved and polypeptides inherently have affinity for tissue proteins. Further, the various functional recitations in the claims are met because the contrast agents of Brixner have the same components as claimed, i.e. an IEM, a PBM and an MS as described above, and same compounds must have the same properties.

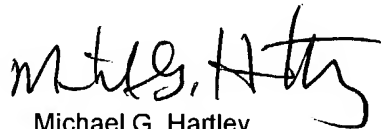
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael G. Hartley
Primary Examiner
Art Unit 1616

12/17/2004